

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of:	Group Art Unit: 1614
MICHAEL PORAT	Examiner: T. Betton
Serial No.: 10/627,968	
Filed: July 28, 2003	

For: AIDS PROPHYLACTIC LUBRICATING COMPOSITION

**DECLARATION UNDER 37 CFR 1.132**

Honorable Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Michael Porat, do hereby declare as follows:

I am the named inventor of the above-identified patent application.

Upon information and belief, I can state that the regular pH of a clean and healthy vagina is between 3.8 and 4.5. During menstruation, it can reach 7.45 and after menopause, pH is between 6 and 7. After intercourse, the pH can reach 7.8. Further, the pH of semen is 7.2 - 7.8 and the pH of blood is 7.34 - 7.45.

From the above, it is apparent that the pH in the vagina is unstable and varies from 3.8 to 7.8.

To the best of my knowledge, Chlorhexidine Gluconate (CHG) is not used commercially as a spermicide, and there is no commercial Chlorhexidine-based spermicidal composition. CHG is known as a surfactant microbicide that does not create ulceration since it is not an aggressive chemical compound.

The earlier lubricant composition K-Y Jelly containing CHG and Methylparaben in small amounts, (0.02% CHG and 0.15% Methylparaben) (Martindale, Extra Pharmacopeia 28th edition, page 955) specified it only as a lubricant.

Benzalkonium Chloride (BZC) and Nonoxynol-9 (Nx-9) are often used together with condoms, cervical caps and diaphragms.

The pH of the following compositions was tested:

Product	pH
K-Y Jelly	6.6-7.0
K-Y Jelly plus (w/2.2% Nx-9)*	6.8
Pharmatex Sponges**	6.7-7.0
Delfen Contraceptive Foam***	6.5-7.1
Ramses Condoms****	6.5-7.2

*\* later compositions, containing significantly more amounts of CHG or Nx9 without increasing the small amount of Methylparaben came on the market after the effective filing date of the present application, and therefore are not prior art.*

*\*\* containing BZC and Nx-9, manufactured by Atlantic Pharm. Prod. Ireland.*

*\*\*\* containing Nx-9, 12.5 wt. %*

*\*\*\*\* condoms lubricated with 5.6 wt. % Nx-9*

(The Centers for Disease Control and Prevention suggests avoiding condoms that are lubricated with Nx-9).

All the above teaches that the pH of the lubricant is not the deciding factor that creates the ulceration on the vaginal walls. The literature indicates that ulceration is created by aggressive chemical compounds, like BZC and Nx-9, or **as discovered by the undersigned, by the fungus *Candida* that multiplies in the absence of the *Lactobacillus* which is destroyed by the known microbicides.** Because of this phenomena, it is important to prevent the fungus from multiplying by means of the fungicides.

All statements made herein of my own knowledge are true, all statements made herein on information and belief are believed to be true, and further, these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of this application or any patent issuing thereon.

*M. Porat*

Michael Porat

July 27<sup>th</sup>, 2009

Date